A Framework to Evaluate Interoperable Data Exchange Models
for Drug Supply Chain Security Act Compliance

by

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ABSTRACT

The United States has one of the safest drug supply chains in the world. However, its security is threatened by new challenges such as counterfeit, diverted, and illegally imported drugs. To counter the new challenges, the Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013, with a 10-year implementation timeframe. As a result, companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023.

The compliance with the DSCSA will enable companies to operate and manage the risks of their supply chains more efficiently. Industry consortiums, such as the Healthcare Distribution Management Association (HDMA), and the industry leaders have recommended various interoperable data exchange models for the implementation of the compliance. However, domestic and international complexities make it difficult to pick the optimal model for the industry.

In this research, we start with categorizing the known data exchange models that can be potentially used by the U.S. pharmaceutical industry. Second, we develop a scorecard methodology based on a framework that considers various factors across the entire supply chain. Next, we examine the categorized models using this scorecard methodology. Lastly, we conclude with recommendations on the data strategy decision for the U.S. pharmaceutical industry.

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